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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,258	12/19/2001	Celal Albayrak	0081.02	2329

21968 7590 06/24/2003

NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER
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WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/24/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/028,258

Applicant(s)

ALBAYRAK, CELAL

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 7.                      6) ☐ Other:

Art Unit: 1617

**DETAILED ACTION**

Claims 1-30 are pending.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "derivatives" in claim 22 (line 3) is vague and indefinite, as the metes and bounds of this claim are unascertainable. What is a derivative? Is it a salt? Is it an acid? Is it the addition of a methyl group? The specification does not define this phrase and one of ordinary skill in the art would not be apprised of its meaning.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17, 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. (WO 97/19676).

Art Unit: 1617

The instant invention is directed toward a process of making microparticles comprising dissolving a polymer in a halogen free solvent that partially water miscible, adding a hydrophilic active agent, mixing the two, and adding an aqueous aqueous surfactant and mixing.

Rossling et al. teach a method of producing morphologically uniform microcapsules. The method comprising dissolving biodegradable polymers in a halogen-free solvent or solvent mixture, and the buffered, hydrophilic active ingredient solution. Then, an aqueous solution that contains a surface-active substance is added to the emulsion, and the solvent is removed by vacuum. The microcapsules are taught as ranging in size from 200nm to 500um.

Polyglycolides, such as glycolide/lactide copolymers are taught as polymers. Acetone, ethanol, alkyl acetates, alkyl formates, triacetin, triethyl citrate, and/or alkyl lactates are taught as solvents. Tris(hydroxymethyl)aminomethane and citrate are taught as buffer solutions. Nonionic surfactants, polyethylene glycol, and others are taught as surfactants. The reference does not teach the solubility parameters of the polymer solvent and the aqueous phase as less than zero and does not teach the preferred ratios of the polymer phase to the surfactant phase. US 6,294,204 relied upon as an English translation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the solubility parameters and ratios of the polymer solvent and the aqueous phase of Rossling et al. because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

The Examiner respectfully points out instant claim 30 is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination

Art Unit: 1617

of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. However, since claim 30 depends on claims 1, 5, 8, 24 or 26, claim 30 is not being rejected under 102(b), though such microparticles are known in the art.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. as applied to claims 1-17 and 20-30 above, and further in view of Setterstrom et al. (6,410,056).

Rossling et al. is applied as discussed above. The reference lacks microspheres and microsponges.

Setterstrom et al. teach that microspheres tend to be more difficult to rupture as compared to microcapsules because of their internal structure is stronger. Microsponges are taught as porous microspheres. See Col. 3, lines 44-56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the microparticles of Rossling et al. into microspheres instead of microcapsules because of the expectation of achieving a formulation that is stronger and does not rupture as easily, thereby producing a formulation that is longer-lasting once ingested.

### ***Conclusion***

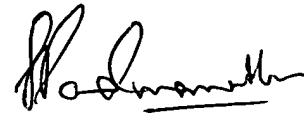
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
May 30, 2003



SREENI PADMANABHAN  
PRIMARY EXAMINER

6/8/03